

# Exhibit D

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION**

**MDL NO. 1968**

**THIS DOCUMENT RELATES TO ALL CASES**

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**DEFENDANTS ACTAVIS TOTOWA LLC,  
ACTAVIS INC., AND ACTAVIS ELIZABETH LLC'S  
RESPONSES TO PLAINTIFFS' SECOND SET OF INTERROGATORIES**

Defendants Actavis Totowa LLC ("Actavis Totowa"), Actavis Inc. ("Actavis"), and Actavis Elizabeth LLC ("Actavis Elizabeth") ("Defendants") respond to Plaintiffs' Second Set of Interrogatories ("Interrogatories") as follows:

**RESERVATION OF RIGHTS**

Defendants respond to Plaintiffs' Interrogatories to the best of their present knowledge, information, and belief. These responses are subject to additional or different information that discovery or further investigation may disclose. Defendants do not waive or intend to waive, by reason of their responses, their rights to: (1) revise, amend, or supplement these responses; (2) object on any ground to the use of documents produced for these responses for any purpose, in whole or in part, in this or any other proceeding, action, or matter; (3) object on any grounds, at any time, to other discovery procedures or requests relating to the subject matter of the Interrogatories; and (4) object on the grounds of admissibility to any documents produced in relation to the responses to these Interrogatories.

**GENERAL OBJECTIONS**

Defendants make the following General Objections, which are in addition to, and incorporated within, each of the specific responses set forth below:

1. Defendants object to Plaintiffs' instructions and definitions to the extent they

attempt to enlarge the scope of permissible discovery under the Federal Rules of Civil Procedure, the Court's Pretrial Orders, and/or any other applicable rules.

2. Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way. As such, Defendants object to the Interrogatories, and the definitions and the instructions, to the extent they imply that Actavis Inc. and Actavis Elizabeth were involved with, or are primary custodians possessing any responsive documents relating to, the manufacture of Digitek®. Furthermore, Defendants assert that the responses set forth herein shall not be considered a waiver of any objection or an acknowledgement by Actavis Inc. and Actavis Elizabeth of involvement with, or possession of responsive documents relating to, the manufacture of Digitek®.

3. Defendants object to Plaintiffs' use of the term "Digitek" to the extent that it pertains to any product not manufactured, distributed, or marketed under the trade name Digitek®. Defendants further object to the extent that Plaintiffs' use of the term "Digitek" includes ingredients or products not manufactured, marketed, or distributed by a party to this lawsuit.

4. Defendants object to each Interrogatory to the extent it seeks any information or document relating to any drug other than Digitek®, the only product at issue in this litigation, which is not also reasonably related to the manufacture of Digitek® except to the extent disclosure of such information is required by the Court's Pre-trial Order #27 in this litigation ("PTO# 27").

5. Defendants object to each Interrogatory to the extent it seeks information or documents protected from disclosure or production by the attorney-client privilege, the attorney work-product doctrine, joint defense or common interest privilege, accountant-client privilege, or by any other privilege or doctrine available under federal or state law, whether statutory, regulatory, constitutional, or common law. Defendants further object to each Interrogatory to the

extent it seeks the disclosure of information or documents protected by statutes, regulations, common law, and the Federal Rules of Civil Procedure that are either absolutely protected from disclosure or production or which should be disclosed or produced only pursuant to an appropriate protective order. Inadvertent disclosure of any such information shall not constitute a waiver of any privilege or any other ground for objecting to discovery with respect to such information, nor shall inadvertent disclosure waive the right of Defendants to object to the use of any such information in any proceeding.

6. Defendants object to each Interrogatory to the extent it seeks discovery or production of confidential, trade secret, and/or proprietary information.

7. Defendants object to each Interrogatory to the extent it calls for the discovery of information already in Plaintiffs' possession, custody, or control, information that is publicly available, or information that is otherwise equally available to Plaintiffs, on grounds that such requests for information are unreasonably cumulative and duplicative, and that such information is obtainable from a source that is more convenient, less burdensome, and less expensive.

8. Defendants object to each Interrogatory to the extent it seeks documents or information relating to the manufacturing and production process of Digitek® batches other than the batches that were the subject of the 2008 Digitek® recall on the grounds that such Interrogatory is overly broad, unduly burdensome, seeks information that is not relevant to the subject matter of this action, and is not reasonably calculated to lead to the discovery of admissible evidence.

9. Defendants object to the extent any Interrogatory seeks information concerning a period of time prior or subsequent to the time period that any Plaintiff allegedly ingested Digitek® on the grounds that such Interrogatory is overly broad, unduly burdensome, and seeks information that is not relevant to the subject matter of this action and is not reasonably calculated to lead to the discovery of admissible evidence.

10. Defendants object to each Interrogatory to the extent it is directed to any entity other than Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC.

11. Defendants object to each Interrogatory to the extent it is vague, ambiguous, confusing, argumentative, overly broad, oppressive, and/or requires an unduly burdensome and unnecessarily expensive search for, and disclosure of, documents that are neither relevant to the claim or defense of any party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

12. Defendants object to each Interrogatory to the extent it is duplicative and cumulative.

13. Defendants object to each Interrogatory to the extent it calls for the disclosure of information or the production of documents not within Defendants' possession, custody, or control.

Defendants respond to these Interrogatories without waiving the foregoing objections (which shall be deemed to apply to each and every Interrogatory), or any other objections set forth herein.

### **RESPONSES TO INTERROGATORIES**

#### **INTERROGATORY NO. 27:**

Please list the "In-house standards" and "USP standards" utilized for Digitek since 1999, the differences between the two standards and why one would be used over the other.

#### **RESPONSE TO INTERROGATORY NO. 27:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms and phrases "In-house standards," "USP standards,"

“differences between the two standards,” and “why one would be used over the other.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Whether a USP Standard or an In-house Standard was used during testing of the recalled batches of Digitek® was within the discretion of Actavis. Typically, Actavis used an In-house Standard if a properly qualified In-house Standard was available and on hand when it was needed during the manufacturing process. See SOP DOI QC-046 “Reference Standard Program,” previously produced (ACTAV 000064253 – ACTAV 000064289). The Standard used during the testing of each recalled batch of Digitek® is indicated in the records relating to the batch. The differences between the Standards used, if any, are reflected in records relating to production of the recalled batches. See previously produced records relating to Batch 70924 (ACTAV 000002112 – ACTAV 000003336), Batch 60236 (ACTAV 000003337 – ACTAV 000003991), Batch 60371 (ACTAV 000003992 – ACTAV 000004240), Batch 60372 (ACTAV 000004241 – ACTAV 000004969), Batch 60373 (ACTAV 000004970 – ACTAV 000005216), Batch 60319 (ACTAV 000006733 – ACTAV 000007669), Batch 60320 (ACTAV 000007670 – ACTAV 000007846), Batch 60321 (ACTAV 000007847 – ACTAV 000008141), Batch 60322 (ACTAV 000008142 – ACTAV 000008307), Batch 60323 (ACTAV 000008308 – ACTAV 000008581), Batch 60399 (ACTAV 000008582 – ACTAV 000008912), Batch 60400 (ACTAV 000008913 – ACTAV 000009153), Batch 60401 (ACTAV 000009154 – ACTAV 000009571), Batch 60402 (ACTAV 000009572 – ACTAV 000009834), Batch 60416 (ACTAV 000009835 – ACTAV 000010090), Batch 60497 (ACTAV 000010091 – ACTAV 000010249), Batch 60498 (ACTAV 000010250 –

ACTAV 000010480), Batch 60499 (ACTAV 000010481 – ACTAV 000010657), Batch 60511 (ACTAV 000010658 – ACTAV 000010863), Batch 60512 (ACTAV 000010864 – ACTAV 000011041), Batch 60513 (ACTAV 0000011042 – ACTAV 000011197), Batch 60514 (ACTAV 000011198 – ACTAV 000011422), Batch 60515 (ACTAV 000011423 – ACTAV 000011585), Batch 60605 (ACTAV 000011586 – ACTAV 000011939), Batch 60606 (ACTAV 000011940 – ACTAV 000012270), Batch 60607 (ACTAV 000012271 – ACTAV 000012658), Batch 60608 (ACTAV 0000012659 – ACTAV 000012920), Batch 60643 (ACTAV 000012921 – ACTAV 000013511), Batch 60644 (ACTAV 000013512 – ACTAV 000013856), Batch 60645 (ACTAV 000013857 – ACTAV 000014119), Batch 60677 (ACTAV 000014120 – ACTAV 000014304), Batch 60678 (ACTAV 000014305 – ACTAV 000014584), Batch 60679 (ACTAV 000014585 – ACTAV 000014833), Batch 60680 (ACTAV 000014834 – ACTAV 000015021), and Batch 60681 (ACTAV 000015022 – ACTAV 000015230), Batch 60756 (ACTAV 000018757 – ACTAV 000019129), Batch 60757 (ACTA000019130 – ACTAV 000019422), Batch 60758 (ACTA000019423 – ACTAV 000019684), Batch 60759 (ACTAV 000019685 – ACTAV 000020107), Batch 60776 (ACTAV 000020108 – ACTAV 000020405), Batch 60777 (ACTAV 000020406 – ACTAV 000020667), Batch 60863, ACTAV 000020668 – ACTAV 000020907), Batch 60864 (ACTAV 000020908 – ACTAV 000021106), Batch 60865 (ACTAV 000021107 – ACTAV 000021291), Batch 60929 (ACTAV 000021292 – ACTAV 000021623), Batch 60930 (ACTAV 000021624 – ACTAV 000021922), Batch 60931 (ACTAV 000021923 – ACTAV 000022282), Batch 60932 (ACTAV 000022283 – ACTAV 000022844), Batch 60991 (ACTAV 000022845 – ACTAV 000023116); (ACTAV 000024284 – ACTAV 000024285), Batch 60992 (ACTAV 000023117 – ACTAV 000023998), Batch 60993 (ACTAV 000023999 – ACTAV 000024352), Batch 60994 (ACTAV 000024353 – ACTAV 000024634), Batch 61053 (ACTAV 000024635 – ACTAV 000024796), Batch 61054 (ACTAV 000024797 – ACTAV 000025095), Batch 61055 (ACTAV 000025096 – ACTAV 000025328), Batch 61056 (ACTAV 000025329 –



ACTAV 000025494), Batch 61057 (ACTAV 000025495 – ACTAV 000025745), Batch 61092 (ACTAV 000025746 – ACTAV 000025985), Batch 61097 (ACTAV 000025986 – ACTAV 000026163), Batch 61098 (ACTAV 000026164 – ACTAV 000026402), Batch 61099 (ACTAV 000026403 – ACTAV 000026605), Batch 61100 (ACTAV 000026606 – ACTAV 000026993), Batch 61101 (ACTAV 000026994 – ACTAV 000027346), Batch 61102 (ACTAV 000027347 – ACTAV 000027639), Batch 61103 (ACTAV 000027640 – ACTAV 000027916), Batch 61104 (ACTAV 000027917 – ACTAV 000028089), Batch 70023 (ACTAV 000029372 – ACTAV 000030541), Batch 70024 (ACTAV 000030542 – ACTAV 000031026), Batch 70025 (ACTAV 000031027 – ACTAV 000031415), Batch 70026 (ACTAV 000031416 – ACTAV 000031779), Batch 70027 (ACTAV 000031780 – ACTAV 000032194), Batch 70078 (ACTAV 000032195 – ACTAV 000033348), Batch 70079 (ACTAV 000033349 – ACTAV 000033715), Batch 70080 (ACTAV 000033716 – ACTAV 000034116), Batch 70081 (ACTAV 000034117 – ACTAV 000034630), Batch 70082 (ACTAV 000034631 – ACTAV 000034995), Batch 70120 (ACTAV 000034996 – ACTAV 000035324), Batch 70121 (ACTAV 000035325 – ACTAV 000035608), Batch 70122 (ACTAV 000035609 – ACTAV 000035907), Batch 70134 (ACTAV 000035908 – ACTAV 000036297), Batch 70135 (ACTAV 000033298 – ACTAV 000036647), Batch 70136 (ACTAV 000033348 – ACTAV 000036996), Batch 70147 (ACTAV 000036997 – ACTAV 000037406), Batch 70149 (ACTAV 000037407 – ACTAV 000037696), Batch 70160 (ACTAV 000037697 – ACTAV 000038158), Batch 70161 (ACTAV 000038159 – ACTAV 000038643), Batch 70174 (ACTAV 000038644 – ACTAV 000038993), Batch 70175 (ACTAV 000038994 – ACTAV 000039349), Batch 70176 (ACTAV 000039350 – ACTAV 000039643), Batch 70207 (ACTAV 000039644 – ACTAV 000040211), Batch 70208 (ACTAV 000040212 – ACTAV 000040628), Batch 70209 (ACTAV 000040629 – ACTAV 000040982), Batch 70296 (ACTAV 000040983 – ACTAV 000041345), Batch 70297 (ACTAV 000041346 – ACTAV 000041651), Batch 70298 (ACTAV 000041652 – ACTAV 000042030), Batch 70299 (ACTAV 000042031 –

ACTAV 000042335), Batch 70300 (ACTAV 000042336 – ACTAV 000042632), Batch 70370 (ACTAV 000042633 – ACTAV 000043156), Batch 70371 (ACTAV 000043157 – ACTAV 000043403), Batch 70372 (ACTAV 000043404 – ACTAV 000043803), Batch 70386 (ACTAV 000043804 – ACTAV 000044081), Batch 70454 (ACTAV 000044082 – ACTAV 000044412), Batch 70455 (ACTAV 000044413 – ACTAV 000044678), Batch 70456 (ACTAV 000044679 – ACTAV 000045023), Batch 70457 (ACTAV 000045024 – ACTAV 000045302), Batch 70458 (ACTAV 000045303 – ACTAV 000045550), Batch 70551 (ACTAV 000045551 – ACTAV 000045939), Batch 70557 (ACTAV 000045940 – ACTAV 000046291), Batch 70558 (ACTAV 000046292 – ACTAV 000046601), Batch 70559 (ACTAV 000046602 – ACTAV 000046920), Batch 70560 (ACTAV 000046921 – ACTAV 000047255), Batch 70600 (ACTAV 000047256 – ACTAV 000047653), Batch 70601 (ACTAV 000047654 – ACTAV 000048017), Batch 70664 (ACTAV 000048018 – ACTAV 000048441), Batch 70665 (ACTAV 000048441 – ACTAV 000048820), Batch 70666 (ACTAV 000048821 – ACTAV 000049097), Batch 70670 (ACTAV 000049098 – ACTAV 000049553), Batch 70671 (ACTAV 000049554 – ACTAV 00004987), Batch 70672 (ACTAV 000049874 – ACTAV 000050183), Batch 70673 (ACTAV 000050184 – ACTAV 000050544), Batch 70736 (ACTAV 000050545 – ACTAV 000051062), Batch 70737 (ACTAV 000051063 – ACTAV 000051414), Batch 70738 (ACTAV 000051415 – ACTAV 000051754), Batch 70753 (ACTAV 000051755 – ACTAV 000052161), Batch 70766 (ACTAV 000052162 – ACTAV 000052611), Batch 70767 (ACTAV 000052611 – ACTAV 000053036), Batch 70768 (ACTAV 000053037 – ACTAV 000053547), Batch 70769 (ACTAV 000053548 – ACTAV 000053976), Batch 70770 (ACTAV 000053977 – ACTAV 000054490), Batch 70811 (ACTAV 000054491 – ACTAV 000054839), Batch 70812 (ACTAV 000054840 – ACTAV 000055172), Batch 70813 (ACTAV 000055173 – ACTAV 000055535), Batch 70832 (ACTAV 000055536 – ACTAV 000055793), Batch 70833 (ACTAV 000055794 – ACTAV 000056198), Batch 70834 (ACTAV 000056199 – ACTAV 000056489), Batch 70835 (ACTAV 000056490 –

ACTAV 000056780), Batch 70836 (ACTAV 000056781 – ACTAV 000057138), Batch 70925 (ACTAV 000057139 – ACTAV 000057468), Batch 70826 (ACTAV 000057469 – ACTAV 000057807), Batch 70949 (ACTAV 000057808 – ACTAV 000058172), Batch 70950 (ACTAV 000058173 – ACTAV 000058544), Batch 70951 (ACTAV 000058545 – ACTAV 000058899), Batch 70952 (ACTAV 000058900 – 000059181), Batch 70953 (ACTAV 000059182 – ACTAV 000059460), Batch 71004 (ACTAV 000059461 – ACTAV 000060005), Batch 71005 (ACTAV 000060006 – ACTAV 000060576), Batch 71032 (ACTAV 000060577 – ACTAV 000061024), Batch 71034 (ACTAV 000061025 – ACTAV 000061473), Batch 71035 (ACTAV 000061474 – ACTAV 000061945), Batch 80111 (ACTAV 000061946 – ACTAV 000062448), Batch 80191 (ACTAV 000062449 – ACTAV 000062685), Batch 80192 (ACTAV 000062686 – ACTAV 000062959). See also the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111.

**INTERROGATORY NO. 28:**

Please list all of the raw ingredients and the manufacturer for each ingredient including active pharmaceutical ingredients and excipients used in the manufacture of Digitek for since 1999.

**RESPONSE TO INTERROGATORY NO. 28:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms “raw ingredients” and “excipients.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants or seeks confidential, trade, secret, or proprietary information protected from disclosure under PTO #12.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing,

distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111.

**INTERROGATORY NO. 29:**

Was the chemical Pyridine used as a precursor or other substance in the purification, extraction, formulation, manufacture, and/or creation of the recalled chemical structural formulation known as Digitek®?

**RESPONSE TO INTERROGATORY NO. 29:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms “precursor” and “recalled chemical structural formulation known as Digitek®.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants or about the manufacturing or production activities of entities other than Defendants. Defendants object to this Interrogatory because it assumes foundational facts that are not in evidence. Defendants further object to this Interrogatory to the extent it seeks information that is not within Defendants’ possession, custody, or control.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Actavis Totowa does not use Pyridine in any aspect of the process of manufacturing Digitek®. To the extent Pyridine

was used by any supplier of any product to Actavis Totowa, it will be reflected in documents to be produced by Defendants on rolling basis, pursuant to PTO #16.

**INTERROGATORY NO. 30:**

Identify all elements, compounds, chemical substances (either organic or non-organic), synthesized compounds, metallic substances, nonmetallic substances, inert gases, and liquid gases which were used as a precursor or other substance in the purification, extraction, formulation, manufacture, and/or creation of the chemical structural formulation known as Digitek®.

**RESPONSE TO INTERROGATORY NO. 30:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms “precursor” and “chemical structural formulation known as Digitek®.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants or about the manufacturing or production activities of entities other than Defendants. Defendants further object to this Interrogatory because it assumes foundational facts that are not in evidence. Defendants further object to this Interrogatory to the extent it seeks information that is not within Defendants’ possession, custody, or control.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111. The elements, compounds, chemical substances (either organic or non-organic),

synthesized compounds, metallic substances, nonmetallic substances, inert gases, and liquid gases used by any supplier of any product to Actavis Totowa will be reflected in documents to be produced by Defendants on rolling basis, pursuant to PTO #16.

**INTERROGATORY NO. 31:**

What quality functions including anything related to quality control or quality assurance was conducted at the Riverview facility, including but not limited to all tests that are performed at this lab? If any, when did the move to Riverview take place?

**RESPONSE TO INTERROGATORY NO. 31:**

Defendants object to this Interrogatory to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. Subject to the provisions of PTO #27, Defendants will not provide any information relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. The inclusion of the phrase “including but not limited to...” also makes this Interrogatory overbroad. This Interrogatory is also vague and confusing as written with respect to the undefined term “quality functions.”

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Actavis Totowa began transferring overall quality control lab operations to the Riverview facility in August, 2007. Quality control testing of Digitek® at the Riverview facility, including testing of raw materials, blend samples, finished product, and stability testing, began in December, 2007. All

of Actavis Totowa's quality control lab functions now are conducted at Riverview. Quality assurance functions relating to certain validation batches of Digitek® that were manufactured as part of Actavis Totowa's efforts to transfer manufacturing operations to Riverview and have the FDA certify the Riverview facility were conducted beginning in December, 2007.

**INTERROGATORY NO. 32:**

What specific machines are used in the manufacture of Digitek® for since 1999, including manufacturer and internal Actavis machine number?

**RESPONSE TO INTERROGATORY NO. 32:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term "internal Actavis machine number." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: The equipment used to manufacture each batch of the recalled Digitek® is identified in the records relating to the manufacture and production of each batch. See previously produced records relating to Batch 70924 (ACTAV 000002112 – ACTAV 000003336), Batch 60236 (ACTAV 000003337 – ACTAV 000003991), Batch 60371 (ACTAV 000003992 – ACTAV 000004240), Batch 60372 (ACTAV 000004241 – ACTAV 000004969), Batch 60373 (ACTAV 000004970 – ACTAV 000005216), Batch 60319 (ACTAV 000006733 – ACTAV 000007669), Batch 60320 (ACTAV 000007670 – ACTAV 000007846), Batch 60321 (ACTAV 000007847 – ACTAV 000008141),



Batch 60322 (ACTAV 000008142 – ACTAV 000008307), Batch 60323 (ACTAV 000008308 – ACTAV 000008581), Batch 60399 (ACTAV 000008582 – ACTAV 000008912), Batch 60400 (ACTAV 000008913 – ACTAV 000009153), Batch 60401 (ACTAV 000009154 – ACTAV 000009571), Batch 60402 (ACTAV 000009572 – ACTAV 000009834), Batch 60416 (ACTAV 000009835 – ACTAV 000010090), Batch 60497 (ACTAV 000010091 – ACTAV 000010249), Batch 60498 (ACTAV 000010250 – ACTAV 000010480), Batch 60499 (ACTAV 000010481 – ACTAV 000010657), Batch 60511 (ACTAV 000010658 – ACTAV 000010863), Batch 60512 (ACTAV 000010864 – ACTAV 000011041), Batch 60513 (ACTAV 000011042 – ACTAV 000011197), Batch 60514 (ACTAV 000011198 – ACTAV 000011422), Batch 60515 (ACTAV 000011423 – ACTAV 000011585), Batch 60605 (ACTAV 000011586 – ACTAV 000011939), Batch 60606 (ACTAV 000011940 – ACTAV 000012270), Batch 60607 (ACTAV 000012271 – ACTAV 000012658), Batch 60608 (ACTAV 0000012659 – ACTAV 000012920), Batch 60643 (ACTAV 000012921 – ACTAV 000013511), Batch 60644 (ACTAV 000013512 – ACTAV 000013856), Batch 60645 (ACTAV 000013857 – ACTAV 000014119), Batch 60677 (ACTAV 000014120 – ACTAV 000014304), Batch 60678 (ACTAV 000014305 – ACTAV 000014584), Batch 60679 (ACTAV 000014585 – ACTAV 000014833), Batch 60680 (ACTAV 000014834 – ACTAV 000015021), and Batch 60681 (ACTAV 000015022 – ACTAV 000015230), Batch 60756 (ACTAV 000018757 – ACTAV 000019129), Batch 60757 (ACTA000019130 – ACTAV 000019422), Batch 60758 (ACTA000019423 – ACTAV 000019684), Batch 60759 (ACTAV 000019685 – ACTAV 000020107), Batch 60776 (ACTAV 000020108 – ACTAV 000020405), Batch 60777 (ACTAV 000020406 – ACTAV 000020667), Batch 60863, ACTAV 000020668 – ACTAV 000020907), Batch 60864 (ACTAV 000020908 – ACTAV 000021106), Batch 60865 (ACTAV 000021107 – ACTAV 000021291), Batch 60929 (ACTAV 000021292 – ACTAV 000021623), Batch 60930 (ACTAV 000021624 – ACTAV 000021922), Batch 60931 (ACTAV 000021923 – ACTAV 000022282), Batch 60932 (ACTAV 000022283 – ACTAV 000022844),



Batch 60991 (ACTAV 000022845 – ACTAV 000023116); (ACTAV 000024284 – ACTAV 000024285), Batch 60992 (ACTAV 000023117 – ACTAV 000023998), Batch 60993 (ACTAV 000023999 – ACTAV 000024352), Batch 60994 (ACTAV 000024353 – ACTAV 000024634), Batch 61053 (ACTAV 000024635 – ACTAV 000024796), Batch 61054 (ACTAV 000024797 – ACTAV 000025095), Batch 61055 (ACTAV 000025096 – ACTAV 000025328), Batch 61056 (ACTAV 000025329 – ACTAV 000025494), Batch 61057 (ACTAV 000025495 – ACTAV 000025745), Batch 61092 (ACTAV 000025746 – ACTAV 000025985), Batch 61097 (ACTAV 000025986 – ACTAV 000026163), Batch 61098 (ACTAV 000026164 – ACTAV 000026402), Batch 61099 (ACTAV 000026403 – ACTAV 000026605), Batch 61100 (ACTAV 000026606 – ACTAV 000026993), Batch 61101 (ACTAV 000026994 – ACTAV 000027346), Batch 61102 (ACTAV 000027347 – ACTAV 000027639), Batch 61103 (ACTAV 000027640 – ACTAV 000027916), Batch 61104 (ACTAV 000027917 – ACTAV 000028089), Batch 70023 (ACTAV 000029372 – ACTAV 000030541), Batch 70024 (ACTAV 000030542 – ACTAV 000031026), Batch 70025 (ACTAV 000031027 – ACTAV 000031415), Batch 70026 (ACTAV 000031416 – ACTAV 000031779), Batch 70027 (ACTAV 000031780 – ACTAV 000032194), Batch 70078 (ACTAV 000032195 – ACTAV 000033348), Batch 70079 (ACTAV 000033349 – ACTAV 000033715), Batch 70080 (ACTAV 000033716 – ACTAV 000034116), Batch 70081 (ACTAV 000034117 – ACTAV 000034630), Batch 70082 (ACTAV 000034631 – ACTAV 000034995), Batch 70120 (ACTAV 000034996 – ACTAV 000035324), Batch 70121 (ACTAV 000035325 – ACTAV 000035608), Batch 70122 (ACTAV 000035609 – ACTAV 000035907), Batch 70134 (ACTAV 000035908 – ACTAV 000036297), Batch 70135 (ACTAV 000033298 – ACTAV 000036647), Batch 70136 (ACTAV 000033348 – ACTAV 000036996), Batch 70147 (ACTAV 000036997 – ACTAV 000037406), Batch 70149 (ACTAV 000037407 – ACTAV 000037696), Batch 70160 (ACTAV 000037697 – ACTAV 000038158), Batch 70161 (ACTAV 000038159 – ACTAV 000038643), Batch 70174 (ACTAV 000038644 – ACTAV 000038993), Batch 70175

(ACTAV 000038994 – ACTAV 000039349), Batch 70176 (ACTAV 000039350 – ACTAV 000039643), Batch 70207 (ACTAV 000039644 – ACTAV 000040211), Batch 70208 (ACTAV 000040212 – ACTAV 000040628), Batch 70209 (ACTAV 000040629 – ACTAV 000040982), Batch 70296 (ACTAV 000040983 – ACTAV 000041345), Batch 70297 (ACTAV 000041346 – ACTAV 000041651), Batch 70298 (ACTAV 000041652 – ACTAV 000042030), Batch 70299 (ACTAV 000042031 – ACTAV 000042335), Batch 70300 (ACTAV 000042336 – ACTAV 000042632), Batch 70370 (ACTAV 000042633 – ACTAV 000043156), Batch 70371 (ACTAV 000043157 – ACTAV 000043403), Batch 70372 (ACTAV 000043404 – ACTAV 000043803), Batch 70386 (ACTAV 000043804 – ACTAV 000044081), Batch 70454 (ACTAV 000044082 – ACTAV 000044412), Batch 70455 (ACTAV 000044413 – ACTAV 000044678), Batch 70456 (ACTAV 000044679 – ACTAV 000045023), Batch 70457 (ACTAV 000045024 – ACTAV 000045302), Batch 70458 (ACTAV 000045303 – ACTAV 000045550), Batch 70551 (ACTAV 000045551 – ACTAV 000045939), Batch 70557 (ACTAV 000045940 – ACTAV 000046291), Batch 70558 (ACTAV 000046292 – ACTAV 000046601), Batch 70559 (ACTAV 000046602 – ACTAV 000046920), Batch 70560 (ACTAV 000046921 – ACTAV 000047255), Batch 70600 (ACTAV 000047256 – ACTAV 000047653), Batch 70601 (ACTAV 000047654 – ACTAV 000048017), Batch 70664 (ACTAV 000048018 – ACTAV 000048441), Batch 70665 (ACTAV 000048441 – ACTAV 000048820), Batch 70666 (ACTAV 000048821 – ACTAV 000049097), Batch 70670 (ACTAV 000049098 – ACTAV 000049553), Batch 70671 (ACTAV 000049554 – ACTAV 00004987), Batch 70672 (ACTAV 000049874 – ACTAV 000050183), Batch 70673 (ACTAV 000050184 – ACTAV 000050544), Batch 70736 (ACTAV 000050545 – ACTAV 000051062), Batch 70737 (ACTAV 000051063 – ACTAV 000051414), Batch 70738 (ACTAV 000051415 – ACTAV 000051754), Batch 70753 (ACTAV 000051755 – ACTAV 000052161), Batch 70766 (ACTAV 000052162 – ACTAV 000052611), Batch 70767 (ACTAV 000052611 – ACTAV 000053036), Batch 70768 (ACTAV 000053037 – ACTAV 000053547), Batch 70769

(ACTAV 000053548 – ACTAV 000053976), Batch 70770 (ACTAV 000053977 – ACTAV 000054490), Batch 70811 (ACTAV 000054491 – ACTAV 000054839), Batch 70812 (ACTAV 000054840 – ACTAV 000055172), Batch 70813 (ACTAV 000055173 – ACTAV 000055535), Batch 70832 (ACTAV 000055536 – ACTAV 000055793), Batch 70833 (ACTAV 000055794 – ACTAV 000056198), Batch 70834 (ACTAV 000056199 – ACTAV 000056489), Batch 70835 (ACTAV 000056490 – ACTAV 000056780), Batch 70836 (ACTAV 000056781 – ACTAV 000057138), Batch 70925 (ACTAV 000057139 – ACTAV 000057468), Batch 70826 (ACTAV 000057469 – ACTAV 000057807), Batch 70949 (ACTAV 000057808 – ACTAV 000058172), Batch 70950 (ACTAV 000058173 – ACTAV 000058544), Batch 70951 (ACTAV 000058545 – ACTAV 000058899), Batch 70952 (ACTAV 000058900 – 000059181), Batch 70953 (ACTAV 000059182 – ACTAV 000059460), Batch 71004 (ACTAV 000059461 – ACTAV 000060005), Batch 71005 (ACTAV 000060006 – ACTAV 000060576), Batch 71032 (ACTAV 000060577 – ACTAV 000061024), Batch 71034 (ACTAV 000061025 – ACTAV 000061473), Batch 71035 (ACTAV 000061474 – ACTAV 000061945), Batch 80111 (ACTAV 000061946 – ACTAV 000062448), Batch 80191 (ACTAV 000062449 – ACTAV 000062685), Batch 80192 (ACTAV 000062686 – ACTAV 000062959). See also the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111.

**INTERROGATORY NO. 33:**

What specific machines have been used in the testing of Digitek® for the past 5 years, including manufacturer, model number and internal Actavis machine number or equipment identification number, including but not limited to those machines used in raw material testing, in-process testing, finished product testing and stability testing?

**RESPONSE TO INTERROGATORY NO. 33:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of

admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. The inclusion of the phrase “including but not limited to...” also makes this Interrogatory overbroad. This Interrogatory is also vague and confusing as written with respect to the undefined terms “internal Actavis machine number or equipment identification number.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: The following manufacturing testing equipment may have been used to test Digitek® at some point during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008. For the specific equipment used to test each specific batch of the recalled Digitek®, see the records relating to the production of the recalled batches, referenced in Defendants’ response to Interrogatory No. 32.

### **THICKNESS GAUGES**

#### **ACTIVE**

<b>System ID</b>	<b>Equipment Type</b>	<b>Manufacturer</b>	<b>Model</b>
TG-0783	Thickness Gauge	Mitutoyo	PK-0505
TG-0784	Thickness Gauge	Mitutoyo	PK-0505
TG-0786	Thickness Gauge	Mitutoyo	PK-0505
TG-0967	Thickness Gauge	Mitutoyo	PK-0505 (700-118)
TG-0973	Thickness Gauge	Mitutoyo	PK-0505
TG-0974	Thickness Gauge	Mitutoyo	PK-0505
TG-0975	Thickness Gauge	Mitutoyo	PK-0505
TG-0976	Thickness Gauge	Mitutoyo	PK-0505
TG-0977	Thickness Gauge	Mitutoyo	PK-0505 (700-118)
TG-0978	Thickness Gauge	Mitutoyo	PK-0505
TG-0979	Thickness Gauge	Mitutoyo	PK-0505
TG-0980	Thickness Gauge	Mitutoyo	PK-0505 (700-118)
TG-0981	Thickness Gauge	Mitutoyo	700-118 PK0505
TG-0982	Thickness Gauge	Mitutoyo	700-118 PK0505

TG-0983	Thickness Gauge	Mitutoyo	700-118 PK0505
TG-0984	Thickness Gauge	Mitutoyo	700-118 PK0505
TG-205920	Thickness Gauge	Mitutoyo	PK0505 (700-118)

**REMOVED FROM SERVICE**

System ID	Equipment Type	Manufacturer	Model
TG-0785	Thickness Gauge	Mitutoyo	PK-0505
TG-0696	Thickness Gauge	Mitutoyo	PK-0505
TG-0968	Thickness Gauge	Mitutoyo	PK-0505
TG-0205299	Thickness Gauge	Mitutoyo	PK-0505
TG-0970	Thickness Gauge	Mitutoyo	PK-0505
TG-0971	Thickness Gauge	Mitutoyo	PK-0505
TG-0972	Thickness Gauge	Mitutoyo	PK-0505

**HARDNESS TESTERS**

System ID	Equipment Type	Manufacturer	Model
HD-251	Hardness Tester	Vankel	VK-200
HD-255	Hardness Tester	Vankel	VK200
HD-257	Hardness Tester	Vankel	40-2000
HD-261	Hardness Tester	Vankel	40-2000
HD-262	Hardness Tester	Vankel	40-2000
HD-263	Hardness Tester	Vankel	40-2000
HD-265	Hardness Tester	Vankel	40-2000
HD-268	Hardness Tester	Vankel	VK-200
HD-3311	Hardness Tester	Vankel	VK200
HD-3312	Hardness Tester	Vankel	VK200

**REMOVED FROM SERVICE**

System ID	Equipment Type	Manufacturer	Model
HD-254	Hardness Tester	Vankel	VK-200
HD-258	Hardness Tester	Vankel	VK-200
HD-264	Hardness Tester	Vankel	VK-200
HD-253	Hardness Tester	Vankel	VK-200

**SCALES****ACTIVE**

System ID	Equipment Type	Manufacturer	Model
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SC-0925	Scale	Ohaus	AR1530
SC-0930	Scale	Ohaus	AR1530
SC-0931	Scale	Ohaus	AR1530
SC-0939	Scale	General	GE525
SC-0940	Scale	General	GE525
SC-0982	Scale	General	GE525
SC-0985	Scale	AND	GP60K
SC-0986	Scale	AND	GF300G
SC-0987	Scale	AND	GF300G
SC-0988	Scale	AND	GF400G
SC-0990	Scale	AND	GP60K
SC-0991	Scale	AND	GP60K
SC-0992	Scale	AND	GP12K
SC-0994	Scale	General	GSE350
SC-0995	Scale	General	GSE350
SC-0996	Scale	General	GSE350
SC-1153	Scale	AND	GP60K
SC-1154	Scale	AND	GP60K
SC-1156	Scale	AND	GF300G
SC-1158	Scale	AND	GP12K
SC-1159	Scale	AND	GP12K
SC-1162	Scale	AND	GSE355
SC-1164	Scale	Mettler Toledo	XS105DU
SC-3211	Scale	AND	GP-12K
SC-3212	Scale	AND	GP-12K
SC-3215	Scale	GSE	355
SC-3216	Scale	GSE	355
<b>FR-0269</b>	<b>Friabilator</b>	<b>Varian</b>	<b>P/N 45-2000</b>

### REMOVED FROM SERVICE

System ID	Equipment Type	Manufacturer	Model
SC-238	Scale	General	GE525
SC-246	Scale	General	GSE350
SC-247	Scale	General	GSE355
SC-226	Scale	Shimadzu	EB63SW
SC-235	Scale	Shimadzu	EB63SW
SC-236	Scale	General	GSE350
SC-926	Scale	Ohaus	AR1530
SC-929	Scale	Ohaus	AR1530
SC-997	Scale	GF	GF-200
SC-998	Scale	GF	GF-200
SC-999	Scale	General	GSE350
SC-3214	Scale	AND	GF-200

SC-3218	Scale	AND	GF-200
SC-218	Scale	Shimadzu	EB63SW
SC-239	Scale	Shimadzu	EB63SW
SC-248	Scale	Ohaus	TS-200
SC-921	Scale	General	GE510
SC-932	Scale	Setra	HP-60K
SC-934	Scale	Setra	12000C
SC-935	Scale	General	GE525
SC-936	Scale	General	GE525
SC-937	Scale	General	GE525
SC-938	Scale	General	GE525
SC-981	Scale	General	GE525

Further answering, the following laboratory testing equipment is currently used by Actavis Totowa to test products and raw materials. Some or all of this equipment may have been used to test Digitek® or raw materials used to make Digitek® at some point during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008. For the specific equipment used to test each specific recalled batch of Digitek® or raw materials used to make the recalled batches of Digitek®, including equipment that is no longer being used for any purpose because it has been taken out of service, see the records relating to the production of the recalled batches, referenced in Defendants' response to Interrogatory No. 32, as well as Logs setting forth the use of such laboratory equipment, to be produced on a rolling basis pursuant to PTO #16.

#### **CURRENT LABORATORY TESTING EQUIPMENT**

<b>Equipment Type</b>	<b>Instrument ID#</b>	<b>Model</b>	<b>Serial Number</b>	<b>Manufacturer</b>
Atomic Absorption	AA-01	AAAnalyst 100	040S1050103	Perkin Elmer Corp.
Micron Air Jet Sieve	AJS-01	Micron Sieves20	33303AJ028	Hosokawa Micron
Micron Air Jet Sieve	AJS-02	Micron Sieves35	08401AJ028	Hosokawa Micron
Micron Air Jet Sieve	AJS-03	Micron Sieves40	0203AJ366	Hosokawa Micron
Micron Air Jet Sieve	AJS-04	Micron Sieves50	03359246	W.S. Tyler



<b>Equipment Type</b>	<b>Instrument ID#</b>	<b>Model</b>	<b>Serial Number</b>	<b>Manufacturer</b>
Micron Air Jet Sieve	AJS-05	Micron Sieves60	33303AJ616	Hosokawa Micron
Micron Air Jet Sieve	AJS-06	Micron Sieves100	33303AJ624	Hosokawa Micron
Micron Air Jet Sieve	AJS-07	Micron Sieves140	33303AJ219	Hosokawa Micron
Micron Air Jet Sieve	AJS-08	Micron Sieves200	33303AJ558	Hosokawa Micron
Micron Air Jet Sieve	AJS-09	Micron Sieves270	33303AJ452	Hosokawa Micron
Micron Air Jet Sieve	AJS-10	Micron Sieves325	33303AJ806	Hosokawa Micron
Micron Air Jet Sieve	AJS-11	Micron Sieves80	33303AJ644	Hosokawa Micron
Micron Air Jet Sieve	AJS-12	Micron Sieves200	33303AJ711	Hosokawa Micron
Micron Air Jet Sieve	AJS-13	Micron Sieves400	29702AJ226	Hosokawa Micron
Micron Air Jet Sieve	AJS-14	Micron Sieves200	USSTD35071 1	Newark Wire Cloth Co.
Micron Air Jet Sieve	AJS-15	Micron Sieves325	USSTD35074 1	Newark Wire Cloth Co.
Micron Air Jet Sieve	AJS-16	Micron Sieves100	USSTD35071 4	Newark Wire Cloth Co.
Bio-Dis Apparatus	BIODIS01	Bio-Dis III  Heater/Circulator-VK750D	18-1160-0307	Varian Inc
Bio-Dis Apparatus	BIODIS02	Bio-Dis III  Heater/Circulator-VK750D	6-3801-0307	Varian Inc
Balance	BL-01	ME235S	21505141	Sartorius
Balance	BL-02	ME235S	21607316	Sartorius
Balance	BL-03	CP225D	19504857	Sartorius
Balance	BL-04	CP225D	21410219	Sartorius
Balance	BL-05	GF200	14675995	AND
Balance	BL-06	GF200	14675994	AND
Balance	BL-07	GF200	14671108	AND
Balance	BL-08	GF2000	14686019	AND
Balance	BL-09	ME-5	16202648	Sartorius
Balance	BL-10	CP225D	16312859	Sartorius
Balance	BL-11-	HR202i	15200214	AND
Balance	BL12	HR202i	15200395	AND
Balance weight Kit	BLWKIT-01	Class-1	70701	Rice Lake
Balance weight Kit	BLWKIT-02	Class-1	70702-70707	Troemner



Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
Balance weight Kit	BLWKIT-03	Class-1	41224	Troemner
Balance weight Kit	BLWKIT-04	Class-1	11441 to 11446	Troemner
Balance weight Kit (Micro)	BLWKIT-05	Class-0	S654	Troemner
Balance weight Kit (Micro)	WT2507	Class-0	S707	Troemner
Digitrate Burette	Burette-01	Jencons Digitrat 50mL	R9890	Jencons
KFT/PAT Burette	Burette-02	Brinkmann 806-10 Exchange Unit	11240092	Metrohm
KFT/PAT Burette	Burette-03	Brinkmann 806-20 Exchange Unit	10974899	Metrohm
KFT/PAT Burette	Burette-04	Brinkmann 506-20 Exchange Unit	11141010	Metrohm
KFT/PAT Burette	Burette-05	Brinkmann 506-20 Exchange Unit	11160580	Metrohm
KFT/PAT Burette	Burette-06	Brinkmann 506-50 Exchange Unit	10540784	Metrohm
KFT/PAT Burette	Burette-07	Brinkmann 739-10 Exchange Unit	N/A	Metrohm
KFT/PAT Burette	Burette-08	Brinkmann 739-20 Exchange Unit	N/A	Metrohm
KFT/PAT Burette	Burette-09	Brinkmann 739-20 Exchange Unit	N/A	Metrohm
KFT/PAT Burette	Burette-10	Brinkmann 739-20 Exchange Unit	N/A	Metrohm
NIST Traceable Resistors	CCKIT-01	Conductivity Calibration Kit	213	Thermo Scientific
NIST Traceable Resistors	CCKIT-02	Conductivity Calibration Kit	268	Thermo Scientific
Centrifuge	CF-01	5804	0012742	Eppendorf
Conductivity Meter with Probe	CM-01	121400 with 013610MD and 013016MD	A04883 WITH G08/034 AND MS2/012	Thermo Scientific

<b>Equipment Type</b>	<b>Instrument ID#</b>	<b>Model</b>	<b>Serial Number</b>	<b>Manufacturer</b>
Digital Callipers	DC-01	3415CC	80216263	Control Company
Digital Callipers	DC-02	799A-12/300	08/110055-1	Starrett
Digital Callipers	DC-03	799A-12/300	08/110053-1	Starrett
Tap Density	DENT-01	Tap Density	5-2197-0307	Varian Inc.
Tap Density	DENT-02	50-1000	5-1875-1002	Varian Inc.
Digital Humidity/Temp. Meter	DHT-01	35519-045	72174616	Control Company
Digital Humidity/Temp. Meter	DHT-02	35519-045	72174603	Control Company
Digital Humidity/Temp. Meter	DHT-03	35519-045	72174602	Control Company
Digital Humidity/Temp. Meter	DHT-04	35519-045	72174604	Control Company
Digital Humidity/Temp. Meter	DHT-05	35519-045	72174859	Control Company
Digital Humidity/Temp. Meter	DHT-06	35519-045	72224140	Control Company
Digital Humidity/Temp. Meter	DHT-07	35519-045	72174608	Control Company
Digital Humidity/Temp. Meter	DHT-08	35519-045	72174681	Control Company
Digital Humidity/Temp. Meter	DHT-09	35519-045	72174606	Control Company
Digital Humidity/Temp. Meter	DHT-10	35519-045	72174613	Control Company
Digital Humidity/Temp. Meter	DHT-11	35519-045	72174588	Control Company
Digital Humidity/Temp. Meter	DHT-12	35519-045	72224164	Control Company
Dissolution Apparatus	DIS013	VK 7000 Heater/circulator-VK750D	1-7773-0307 6-3795-0307	Varian Inc. Varian Inc.

Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
Dissolution Apparatus	DIS02	10-1200 Heater/circulator-VK750D	1-4575-0498 6-3882-067	Vankel Inc Varian Inc
Dissolution Apparatus	DIS03	Evolution 6300 TCS	6301175 2133784	Distek Inc Distek Inc
Dissolution Apparatus	DIS04	Evolution 6300 TCS	6301193 2133905	Distek Inc Distek Inc
Dissolution Apparatus	DIS05	Evolution 6300 TCS	6301191 2133903	Distek Inc Distek Inc
Dissolution Apparatus	DIS06	Evolution 6300 TCS	6301192 2133904	Distek Inc Distek Inc
Dissolution Apparatus	DIS07	10-1600 Heater/circulator-VK750D	1-5783-0401 6-3865-0507	Vankel Inc Varian Inc
Dissolution Apparatus	DIS08	10-1600 Heater/circulator-VK750D	1-6145-0102 6-2710-0504	Vankel Inc Varian Inc
Dissolution Apparatus	DIS09	10-1920 65-3000	1-5784-0401 6-1975-0102	Vankel Inc Vankel Inc.
Dissolution Autosampler	DISAS-01	Evolution 4300 Syringe Pump A/B	4301439 SP01819/SP01820	Distek Inc. Distek Inc
Dissolution Autosampler	DISAS-02	Evolution 4300 Syringe Pump A/B	4301440 SP01821/SP01822	Distek Inc. Distek Inc
Dissolution Center gauge	DISCC-01	170	3117	Distek Inc
Dissolution Height gauge	DISHC-01	180	11001	Distek Inc
Dissolution Calibratin QAkut	DISQA-01	QAII C	24-0102-0707	Varian Inc
Dry Keeper	DK-01	None	4578	Scienceware
Dry Keeper	DK-02	None	4600	Scienceware
Dry Keeper	DK-03	None	4584	Scienceware
Dry Keeper	DK-04	None	4606	Scienceware
Dry Keeper	DK-05	None	4577	Scienceware
Dry Keeper	DK-06	None	4583	Scienceware

<b>Equipment Type</b>	<b>Instrument ID#</b>	<b>Model</b>	<b>Serial Number</b>	<b>Manufacturer</b>
Dry Keeper	DK-07	None	4587	Scienceware
Dry Keeper	DK-08	None	4580	Scienceware
Digital Manometer	DM-001	HHP242-015A	0912000030	Omega Engineering
Digital Manometer	DM-002	HHP242-015A	0912000031	Omega Engineering
Digital Manometer	DM-003	HHP242-015A	0912000029	Omega Engineering
Disintegration Apparatus	DT01	VK 100	36-575-0307	Varian Inc
Digital Thermometer w/Probe	DTH-003	1523/ 08500-96	9877117/T01	Fluke/Cole Parmer
Digital Thermometer w/Probe	DTH-007	TFX430/TPX130	10408718/10401568	EBRO
Digital Thermometer w/Probe	DTH-008	TFX430/TPX130	10408705/10401566	EBRO
Digital Thermometer w/Probe	DTH-009	TFX430/TPX130	10408704/10401565	EBRO
Digital Thermometer w/Probe	DTH-010	TFX430/TPX130	10408703/10401564	EBRO
Digital Thermometer w/Probe	DTM-02	800024	060802157/A02	Sper Scientific
Digital Thermometer w/Probe	DTM-03	OMEGA/ON-402-PP	306985/08K27883	Omega
Digital Thermometer w/Probe	DTM-04	1523-5627A	9794037/821399	Fluke
Digital Thermometer w/Probe	DTM-05	1523/5611T	9762064/A910507	Fluke
Dissolution Vessel Washer	DW-01	VIP400	4401052	Distek Inc
Friabilator	FR01	Friabilator	4-2422-0107	Varian Inc
Friabilator	FR-02	45-1000	4-2075-1002	Vankel Inc
Freezer	FRZ-01	MFP-2020	WB70941341-0707	Lab Research Products
GC	GC-001	6890N COMBI PAL	CN10639012127932	Agilent
GC	GC-002	6890N COMBI PAL	CN10731008128309	LEAP Technology

Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
GC	GC-003	6890N	CN10641031	Agilent
		7683 B ALS	CN63835694	Agilent
		7683 ALS Tray	CN63941255	Agilent
		G1888 Headspace Sampler	IT00628001	Agilent
Interface Module (CG-Little Falls Facility)	GC17	900	8075252722	PE Nelson
GC Clow Meter	GCFM-01	ADM1000	US07A31743	Agilent/HP
Drying Oven	GDO-01	FD53-UL	07-19842	Binder
Miele glassware Washer	GW-01	G7883CD	74324616	Distek Inc
Height Gage	HG-01	3752	08137046	Starrett
Hardness Tester	HG01	VK-200	8-1868-0307	Varian Inc
Hardness Tester	HG-02	40-2000	8-1002-0599	Vankel Inc
Incufridge	ICF-01	None	None	Revolutionary Science
Auto Titrator	KFT-01	795	1795001011190	Brinkmann
Auto Titrator	KFT-02	702 SM	ON5-102	Brinkmann
HPLC	LC001	Alliance 2695 Separation module	CO7SM4618A	Waters Corp.
		2487 UV-Vis Dual Absorbance Detector **	C07587805M	Waters Corp.
		Column Heater	A07SMC471E	Waters Corp.
HPLC	LC002	Alliance 2695 Separation module	C07SM4573A	Waters Corp.
		2487 UV-Vis Dual Absorbance Detector **	C07487802M	Waters Corp.
		Column Heater	A07SMC464E	Waters Corp.

Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
HPLC	LC003	Alliance 2695 Separation module	C07SM4572A	Waters Corp.
		2487 UV-Vis Dual Absorbance Detector **	C07487810M	Waters Corp.
		Column Heater	A07SMC438 E	Waters Corp.
		2414 Refractive Index detector	B07214495M	Waters Corp.
HPLC	LC008	Alliance 2695 Separation module	F07SM4297A	Waters Corp.
		2487 UV-Vis Dual Absorbance Detector **	G07487700M	Waters Corp.
		Column Heater	E07SMC878E	Waters Corp.
HPLC	LC009	Alliance 2695 Separation module	F07SM4304A	Waters Corp.
		2487 UV-Vis Dual Absorbance Detector **	G07487703M	Waters Corp.
		Column Heater	E07SMC882E	Waters Corp.
HPLC	LC010	LC-2010cHT	C2125420398 8LP	Shimadzu Corp.
HPLC	LC011	LC-2010cHT	C2125440474 0 LP	Shimadzu Corp
HPLC	LC012	LC-2010cHT	C2125440472 1LP	Shimadzu Corp
HPLC	LC013	LC-2010cHT	C2125440472 3 LP	Shimadzu Corp
HPLC	LC014	Alliance 2695 Separation module	K07SM42141 A	Waters Corp.
		2489 UV-Vis	K0787E827M	Waters Corp.

Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
		Detector		
		Column Heater	K07SMC572	
		2414	E	
		Refractive	K07214041M	Waters Corp.
		Index detector		Waters Corp.
HPLC	LC015	Alliance 2695	K07SM4251	Waters Corp.
		Seperation module	A	
		2998	L07998806N	Waters Corp.
		Photodiode Array Detector		
		Column Heater	K07SMC540	Waters Corp.
			E	
HPLC	LC016	Alliance 2695	K07SM4248	Waters Corp.
		Seperation module	A	
		2489 UV-Vis	K0787E812M	Waters Corp.
		Detector		
		Column Heater	K07SMC538	Waters Corp.
			E	
HPLC	LC017	Alliance 2695	K07SM4245	Waters Corp.
		Seperation module	A	
		2998	K07998636N	Waters Corp.
		Photodiode Array Detector		
		Column Heater	K07SMC569	Waters Corp.
			E	
HPLC	LC018	Alliance 2695	K07SM4252	Waters Corp.
		Seperation module	A	
		2489 UV-Vis	K0787E878M	Waters Corp.
		Detector		
		Column Heater	K07SMC553	Waters Corp.
			E	
		2414	K07214020M	Waters Corp.
		Refractive		

Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
		Index detector		
HPLC	LC019	Alliance 2695 Separation module	K07SM4258 A	Waters Corp.
		2998 Photodiode Array Detector	L07998796N	Waters Corp.
		Column Heater	K07SMC556 E	Waters Corp.
HPLC	LC020	LC-2010cHT	C2125420398 1 LP	Shimadzu Corp.
HPLC	LC021	LC-2010cHT	C2125420398 2 LP	Shimadzu Corp.
HPLC	LC022	LC-2010cHT	C2125420398 4 LP	Shimadzu Corp.
HPLC	LC023	LC-2010cHT	C2125440473 0 LP	Shimadzu Corp.
HPLC	LC024	LC-2010cHT	C2125440472 7 LP	Shimadzu Corp.
HPLC	LC025	LC-2010cHT	C2125440472 8 LP	Shimadzu Corp.
Micron Air Jet Sieve	MAJ-01	N/A	277097-71287	Hosokawa Micron
Malvern Mastersizer	MAL-01	MS-200	MAL1009984	Malvern Instruments Limited
		Hydro S	MAL1010334	Malvern Instruments Limited
		Scirocco	MAL1010002	Malvern Instruments Limited
Moisture Balance	MB-01	MB45	1128023496	Ohaus
Distek EZ Fill 4500	MD-01	ez Fill 4500	4501028	Distek Inc
Distek EZ Fill 4500	MD-02	ez Fill 4500	4501029	Distek Inc
Muffle Furnace	MF-01	FB1415M	12570702367 84	Barnstead
Micrometer	MM-01	C0030025	N/A	Starrett
Melting Point Apparatus	MPA-01	Optimelt	78323	Stanford Research System



<b>Equipment Type</b>	<b>Instrument ID#</b>	<b>Model</b>	<b>Serial Number</b>	<b>Manufacturer</b>
Wrist Shaker	MS-01	75	183070763	Burrell Scientific
Wrist Shaker	MS-02	75	183070925	Burrell Scientific
Wrist Shaker	MS-03	75	183070916	Burrell Scientific
Wrist Shaker	MS-04	75	183070859	Burrell Scientific
Wrist Shaker	MS-05	75	183070855	Burrell Scientific
Drying Oven	OV-01	FD53-UL	07-19841	Binder
Drying Oven	OV -02	FD53-UL	07-19840	Binder
Auto Titrator	PAT-01	798 MPT TITRINO	1798001010264	Brinkmann
Auto Titrator	PAT-02	716 DMS	40104	Brinkmann
Electronic Thermostat	PC-01	PT31	25031109260808	Rudolph Instruments
ELGA PureLab Ultra water System	PFW-01	Uktra Analytic MK1	UAB23584	ELGA
pH Meter	pH-01	SB70P	005527	VWR Symphony
pH Meter	pH-02	SB70P	005526	VWR Symphony
pH Meter	pH-03	SB70P	005702	VWR Symphony
pH Meter	pH-04	SB70P	005252	VWR Symphony
Polarimeter	PM-01	341	8854	Perkin Elmer Corp.
PhotoTachometer	PTC-01	N/A	Q041969	VWR
Pycnometer Thermometer	PTH-01	N/A	579467	Kontes
Pycnometer Thermometer	PTH-03	N/A	579376	Kontes
Digital Timer	QC-DT-01	5004CC	80477275	Control Company
Digital Timer	QC-DT-02	5004CC	80477276	Control Company
Digital Timer	QC-DT-03	5004CC	80477277	Control Company
Digital Timer	QC-DT-04	5004CC	80477278	Control Company
Digital Timer	QC-DT-05	5004CC	80477279	Control Company
Digital Timer	QC-DT-06	5004CC	80477280	Control Company

<b>Equipment Type</b>	<b>Instrument ID#</b>	<b>Model</b>	<b>Serial Number</b>	<b>Manufacturer</b>
Digital Timer	QC-DT-07	5004CC	80477281	Control Company
Digital Timer	QC-DT-08	5004CC	80477282	Control Company
Digital Timer	QC-DT-09	5004CC	80477283	Control Company
Digital Timer	QC-DT-10	5004CC	80477284	Control Company
Digital Timer	QC-DT-11	5004CC	80477285	Control Company
Digital Timer	QC-DT-12	5004CC	80477286	Control Company
Digital Timer	QC-DT-13	5004CC	80477287	Control Company
Digital Timer	QC-DT-14	5004CC	80477288	Control Company
Digital Timer	QC-DT-15	5004CC	80477289	Control Company
Digital Timer	QC-DT-16	5004CC	80477290	Control Company
Digital Timer	QC-DT-17	5004CC	80477291	Control Company
Digital Timer	QC-DT-18	5004CC	80477292	Control Company
Digital Timer	QC-DT-19	5004CC	80477293	Control Company
Digital Timer	QC-DT-20	5004CC	80477294	Control Company
Digital Timer	QC-DT-21	5004CC	80477295	Control Company
Digital Timer	QC-DT-22	5004CC	80477296	Control Company
Digital Timer	QC-DT-23	5004CC	80477297	Control Company
Digital Timer	QC-DT-24	5004CC	80477298	Control Company
Digital Timer	QC-DT-25	5004CC	80477299	Control Company
Digital Timer	QC-DT-26	5004CC	80477300	Control Company
Digital Timer	QC-DT-27	5004CC	80477301	Control Company
Digital Timer	QC-DT-28	5004CC	80477302	Control Company
Digital Timer	QC-DT-29	5004CC	80477303	Control Company

<b>Equipment Type</b>	<b>Instrument ID#</b>	<b>Model</b>	<b>Serial Number</b>	<b>Manufacturer</b>
Digital Timer	QC-DT-30	5004CC	80477304	Control Company
Digital Timer	QC-DT-31	5004CC	80477305	Control Company
Digital Timer	QC-DT-32	5004CC	80477306	Control Company
Digital Timer	QC-DT-33	5004CC	80477307	Control Company
Digital Timer	QC-DT-34	5004CC	80477308	Control Company
Digital Timer	QC-DT-35	5004CC	80477309	Control Company
Digital Timer	QC-DT-36	5004CC	80477310	Control Company
Digital Timer	QC-DT-37	5004CC	80477311	Control Company
Digital Timer	QC-DT-38	5004CC	80477312	Control Company
Digital Timer	QC-DT-39	5004CC	80477313	Control Company
Digital Timer	QC-DT-40	5004CC	80477314	Control Company
Digital Timer	QC-DT-41	5004CC	80477315	Control Company
Digital Timer	QC-DT-42	5004CC	80477316	Control Company
Digital Timer	QC-DT-43	5004CC	80477317	Control Company
Digital Timer	QC-DT-44	5004CC	80477318	Control Company
Digital Timer	QC-DT-45	5004CC	80477319	Control Company
Digital Timer	QC-DT-46	5004CC	80477320	Control Company
Digital Timer	QC-DT-47	5004CC	80477321	Control Company
Digital Timer	QC-DT-48	5004CC	80477322	Control Company
Digital Timer	QC-DT-49	5004CC	80477323	Control Company
Digital Timer	QC-DT-50	5004CC	80477324	Control Company
Ultrasonic (Sonicator)	QC-S1	8510R-DTH	RPC110735530F	Branson
Ultrasonic (Sonicator)	QC-S2	8510R-DTH	RPC050724117E	Branson

Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
Ultrasonic (Sonicator)	QC-S3	8510R-DTH	RPC020719312E	Branson
Ultrasonic (Sonicator)	QC-S4	8510R-MT	RPA100595808E	Branson
Ultrasonic (Sonicator)	QC-S5	8510R-MT	RP Ai 00154883 E	Branson
262-0066"1 150MM Rule	RC-01	None	500410524	Engineering
Conductivity/Resistivity Meter	RES02	200CR	607070017	Mettler Toledo Thornton
Refractometer	RF-01	334610	345K018001	Thermo Electron Corporation
Refrigerator	RFG-01	LRP - 26	1-4844204-0707	Lab Research Products
Radio/ Photo Meter	RPM-01	IL1400A	6588	International Light
		UV/VIS Detector -- SEL033	7265/7255	International Light
Photochemical Reactor	RPR-01	None	None	N/A
Ro-Tap	RTSS-01	E	16040	W.S. Tyler
Sonic Sifter	SS-01	L3P	6117	Advantech Mfg.
Sonic Sifter Sieve	SSS-Oi	Sonic Sifter Sieve20	20C7	AdvanTech
Sonic Sifter Sieve	555-02	Sonic Sifter Sieve40	40D7	AdvanTech
Sonic Sifter Sieve	555-03	Sonic Sifter Sieve60	60F7	AdvanTech
Sonic Sifter Sieve	555-04	Sonic Sifter Sieve80	BOF7	AdvanTech
Sonic Sifter Sieve	555-05	Sonic Sifter Sieve100	100F7	AdvanTech
Sonic Sifter Sieve	555-06	Sonic Sifter Sieve120	120F7	AdvanTech
Sonic Sifter Sieve	555-07	Sonic Sifter Sieve140	140B7	AdvanTech
Sonic Sifter Sieve	555-08	Sonic Sifter Sieve170	170G7	AdvanTech
Sonic Sifter Sieve	SSS-09	Sonic Sifter Sieve200	200F7	AdvanTech
Sonic Sifter Sieve	555-10	Sonic Sifter Sieve230	230E7	AdvanTech

Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
Sonic Sifter Sieve	S5S-11	Sonic Sifter Sieve270	270F7	AdvanTech
Sonic Sifter Sieve	555-12	Sonic Sifter Sieve325	325£7	AdvanTech
Scott Volumeter	SV -01	None	N/A	N/A
Scott Volumeter	SV-02	None	N/A	NJA
Steam Water bath	SWB-01	None	603081453	Precision
Tachometer	TC-01	4262	61700941	Control Company
Long Stem Thermometer	QC-TH-01	4352CC	72515219	Control Company
Long Stem Thermometer	QC-TH-02	4352CC	72515246	Control Company
Long Stem Thermometer	QC-TH-04	4352CC	72515252	Control Company
Long Stem Thermometer	QC- TH-05	4352CC	72515259	Control Company
Long Stem Thermometer	QC- TH-06	4352CC	72515262	Control Company
Long Stem Thermometer	QC- TH-07	4352CC	72515264	Control Company
Long Stem Thermometer	QC- TH-08	4352CC	72515266	Control Company
Long Stem Thermometer	QC- TH-09	4352CC	72515277	Control Company
Long Stem Thermometer	QC-TH-10	4352CC	72515282	Control Company
Long Stem Thermometer	QC-TH-11	4352CC	72515288	Control Company
Long Stem Thermometer	QC-TH-12	4352CC	72523291	Control Company
Long Stem Thermometer	TH-13	4352CC	80285745	Control Company
Long Stem Thermometer	TH ·14	4352CC	80285748	Control Company
Long Stem Thermometer	TH-15	4352CC	80285749	Control Company
Long Stem Thermometer	TH-16	4352CC	80285751	Control Company
Long Stem Thermometer	TH-17	4352CC	80285753	Control Company
Long Stem Thermometer	TH-19	4352CC	80285756	Control Company
Long Stem Thermometer	TH-20	4352CC	80285757	Control Company
Long Stem Thermometer	TH-21	4352CC	80285760	Control Company

<b>Equipment Type</b>	<b>Instrument ID#</b>	<b>Model</b>	<b>Serial Number</b>	<b>Manufacturer</b>
Long Stem Thermometer	TH - 22	4352CC	80285770	Control Company
Long Stem Thermometer	TH-23	4352CC	80285773	Control Company
Long Stem Thermometer	TH-24	4352CC	72335582	Control Company
Tyler Sieve	TS-02	Tyler Sieve20	07296708	W.S.Tyler
Tyler Sieve	TS-03	Tyler Sieve40	07296709	W.S.Tyler
Tyler Sieve	TS-04	Tyler Sieve60	07296710	W.S.Tyler
Tyler Sieve	TS-05	Tyler Sieve80	07296711	W.S.Tyler
Tyler Sieve	TS-07	Tyler Sieve140	07296713	W.S.Tyler
Tyler Sieve	TS-08	Tyler Sieve200	07296714	W.S.Tyler
Tyler Sieve	TS-10	Tyler Sieve400	07296716	W.S.Tyler
Tyler Sieve	TS-11	Tyler Sieve25	03012208	Retsch
Tyler Sieve	TS-12	Tyler Sieve30	08129238	W.S.Tyler
Tyler Sieve	TS-13	Tyler Sieve35	04021202	Retsch
Tyler Sieve	TS-14	Tyler SieveSO	04026783	Retsch
Tyler Sieve	TS-15	Tyler Sieve325	06419162	W.S.Tyler
Tyler Sieve	TS-16	Tyler Sieve325	USSTD70301	Newark Wire Cloth Company
Tyler Sieve	TS-17	Tyler Sieve100	USSTD71100	Newark Wire
Tyler Sieve	TS-18	Tyler Sieve60	USSTD70501	Newark Wire
Tyler Sieve	TS-19	Tyler Sieve200	USSTD71200	Newark Wire
Tyler Sieve	TS- 20	Tyler Sieve18	USSTD70018	Newark Wire
Tyler Sieve	TS-21	Tyler Sieve40	USSTD70203	Newark Wire
Tyler Sieve Shaker	TSS-01	RX-86	573	W.S.Tyler
UV-Vis Spectrophotometer	UV01	UV-1700	A1102443680 0CS	Shimadzu Corp.
Syringe Sipper	UVS01	Syringe Sipper N	A1101440029 5	Shimadzu Corp.
UV-Vis Spectrophotometer	UV02	UV-1601	A1 07540021 98 LP	Shimadzu Corp.
Syringe Sipper	UVS02	Syringe Sipper N	A1101440026 6 TK	Shimadzu Corp.
UV-Vis Spectrophotometer	UV-03	UV-1601	Ai 07540851 09 SM	Shimadzu Corp.
Syringe Sipper	UVS03	Syringe Sipper N	A1101440033 7 TK	Shimadzu Corp.
UV Light Chamber	UVL -01	None	1405	Camag
Density Cup	VDC-01	20-0009	06-1 84	Steiner enterprises Inc
Density Cup	VDC -02	20-0009	07-056	Steiner enterprises Inc
Vacuum/Pressur Gauge	VG-01	3166	61844164	Control Company

Equipment Type	Instrument ID#	Model	Serial Number	Manufacturer
Vaccum Oven	VO-01	ADP21	ADP200B7400013	Yamato
Vaccum Oven	VO-OZ	ADPZ1	ADP200B7X00186	Yamato
Vaccum Oven	VO-03	ADP21	ADP200B7X00188	Yamato
Water bath	WB-01	18012	1475070706676	Barnstead international
Water bath	WB-03	205	1600080453541	Fisher Scientific Inc

**INTERROGATORY NO. 34:**

For each machine, listed in your answers to the above interrogatories, please list what other products each machine is used to manufacture and/or test.

**RESPONSE TO INTERROGATORY NO. 34:**

Defendants object to this Interrogatory to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. Subject to the provisions of PTO #27, Defendants will not provide any information relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. This Interrogatory is also vague and confusing as written with respect to the undefined phrase “used to manufacture and/or test.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See Equipment

Usage and Cleaning Logs, previously produced (ACTAV 000015231 – ACTAV 000018681; ACTAV – 0028090 – ACTAV 000028177; ACTAV 000062903 – ACTAV 000062943). Additional documents containing information that is responsive to this Interrogatory, if any, will be produced on a rolling basis pursuant to PTO #16.

**INTERROGATORY NO. 35:**

Please list all analysts that performed any testing since 1999 on Digitek® or the component parts or raw materials used in the manufacturing of Digitek®. For each analyst named, please state whether they are currently employed and the bates numbers for that person's corresponding lab notebook.

**RESPONSE TO INTERROGATORY NO. 35:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term “analyst.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants and information that is beyond the possession, custody, and control of Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: To the best of Defendants' knowledge, the following individuals have been involved with testing of products or raw materials for Actavis Totowa at some point during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008, and may have been involved in testing Digitek® or the raw materials used to make Digitek®. The identity of some former employees of Amide



(predecessor to Actavis Totowa) who performed testing of products or raw materials and who may have performed testing of Digitek® or the raw materials used to make Digitek® is not known to and is not readily accessible to Defendants. If Defendants learn of additional responsive information, Defendants will timely supplement this response.

Current Employees

1. Jigneshkumar C. Soni
2. Dilipkumar R Patel
3. Jitendra D Patel
4. Manish I Patel
5. Bakul J Shah
6. Kalpesh H Shah
7. Jyotiben P Panchal
8. Harshika K Patel
9. Majlinda L Xhelo
10. Pranathi Neelam
11. Kwame Adjei
12. Anilkumar Patel
13. Dinesh R Patel
14. Maheshbhai S Patel
15. Nimeshkumar N Patel
16. Ritaben R Patel
17. Kazi M Rahman
18. Girishchandra B Upadhyay
19. Daniel J Burns
20. Kishor N Lad

21. Harshad A Patel
22. Hemlataben Patel
23. Ketankumar A Patel
24. Narendrakumar J Patel
25. Paresh M Patel
26. Sanjay N Patel
27. Jigneshkumar I Desai
28. Pratik P Kalaria
29. Devang B Patel
30. Pratik S Patel
31. Sunilkumar S Patel
32. Kaushik R Soni
33. Hemang P Kapadia
34. Gaurang L Pandya
35. Tarak M Shah
36. Chintan M Joshi
37. Tushar R Malkan
38. Justine V Parmar
39. Chiragbhai S Patel
40. Hiteshkumar N Patel
41. Jitenbhai R Patel
42. Mahendrakumar B Patel
43. Nimishkumar C Patel
44. Madhulika Joshi
45. Haresh G Patel

46. Sonal M Patel
47. Umang B Pandya
48. Inaben M Patel
49. Nikunj Kumar J Patel
50. Rajendrakumar P Patel
51. Saurabh Kumar J Patel
52. Shitalbaben H Patel
53. Emiliya I Antonova
54. Chetan J Rana
55. Kinjal M Maniar
56. Hardik V Parikh
57. Chirag V Patel
58. Dilip Kumar C Patel
59. Girish T Rana
60. Hemant Kumar P Rao
61. Shilpa D Patel
62. Nikhil B Patel
63. Ritesh Kumar S Patel

Former Employees

64. Niles Kumar C Patel
65. Bharat G Rana
66. Yamal Y Bhagat
67. Ansuyaben J Patel
68. Ashish Kumar J Patel
69. Dharmeshbhai C Patel

70. Indradaman V Shah
71. Mohammed Zaman
72. Chandubhai D Patel
73. Chandrakant C Desai
74. Anjan Shah
75. Arpita Shingala
76. Ritenkumar P Pandya
77. Ambalal Patel
78. Jayeshkumar M Patel
79. Vinubhai N Patolia
80. Gauri N Tamhane
81. Amit Shah
82. Harshadbhai P. Patel
83. Gautamumar N. Ajmeri
84. Amblal C. Patel
85. Amit R. Shahh

Further answering, see the lab notebooks and other parts of batch records of the recalled batches of Digitek® which have been produced identifying the individuals who performed testing in connection with those batches of Digitek®. See: records relating to Batch 70924 (ACTAV 000002112 – ACTAV 000003336), Batch 60236 (ACTAV 000003337 – ACTAV 000003991), Batch 60371 (ACTAV 000003992 – ACTAV 000004240), Batch 60372 (ACTAV 000004241 – ACTAV 000004969), Batch 60373 (ACTAV 000004970 – ACTAV 000005216), Batch 60319 (ACTAV 000006733 – ACTAV 000007669), Batch 60320 (ACTAV 000007670 – ACTAV 000007846), Batch 60321 (ACTAV 000007847 – ACTAV 000008141), Batch 60322 (ACTAV 000008142 – ACTAV 000008307), Batch 60323 (ACTAV 000008308 – ACTAV

000024285), Batch 60992 (ACTAV 000023117 – ACTAV 000023998), Batch 60993 (ACTAV 000023999 – ACTAV 000024352), Batch 60994 (ACTAV 000024353 – ACTAV 000024634), Batch 61053 (ACTAV 000024635 – ACTAV 000024796), Batch 61054 (ACTAV 000024797 – ACTAV 000025095), Batch 61055 (ACTAV 000025096 – ACTAV 000025328), Batch 61056 (ACTAV 000025329 – ACTAV 000025494), Batch 61057 (ACTAV 000025495 – ACTAV 000025745), Batch 61092 (ACTAV 000025746 – ACTAV 000025985), Batch 61097 (ACTAV 000025986 – ACTAV 000026163), Batch 61098 (ACTAV 000026164 – ACTAV 000026402), Batch 61099 (ACTAV 000026403 – ACTAV 000026605), Batch 61100 (ACTAV 000026606 – ACTAV 000026993), Batch 61101 (ACTAV 000026994 – ACTAV 000027346), Batch 61102 (ACTAV 000027347 – ACTAV 000027639), Batch 61103 (ACTAV 000027640 – ACTAV 000027916), Batch 61104 (ACTAV 000027917 – ACTAV 000028089), Batch 70023 (ACTAV 000029372 – ACTAV 000030541), Batch 70024 (ACTAV 000030542 – ACTAV 000031026), Batch 70025 (ACTAV 000031027 – ACTAV 000031415), Batch 70026 (ACTAV 000031416 – ACTAV 000031779), Batch 70027 (ACTAV 000031780 – ACTAV 000032194), Batch 70078 (ACTAV 000032195 – ACTAV 000033348), Batch 70079 (ACTAV 000033349 – ACTAV 000033715), Batch 70080 (ACTAV 000033716 – ACTAV 000034116), Batch 70081 (ACTAV 000034117 – ACTAV 000034630), Batch 70082 (ACTAV 000034631 – ACTAV 000034995), Batch 70120 (ACTAV 000034996 – ACTAV 000035324), Batch 70121 (ACTAV 000035325 – ACTAV 000035608), Batch 70122 (ACTAV 000035609 – ACTAV 000035907), Batch 70134 (ACTAV 000035908 – ACTAV 000036297), Batch 70135 (ACTAV 000033298 – ACTAV 000036647), Batch 70136 (ACTAV 000033348 – ACTAV 000036996), Batch 70147 (ACTAV 000036997 – ACTAV 000037406), Batch 70149 (ACTAV 000037407 – ACTAV 000037696), Batch 70160 (ACTAV 000037697 – ACTAV 000038158), Batch 70161 (ACTAV 000038159 – ACTAV 000038643), Batch 70174 (ACTAV 000038644 – ACTAV 000038993), Batch 70175 (ACTAV 000038994 – ACTAV 000039349), Batch 70176 (ACTAV 000039350 – ACTAV

000039643), Batch 70207 (ACTAV 000039644 – ACTAV 000040211), Batch 70208 (ACTAV 000040212 – ACTAV 000040628), Batch 70209 (ACTAV 000040629 – ACTAV 000040982), Batch 70296 (ACTAV 000040983 – ACTAV 000041345), Batch 70297 (ACTAV 000041346 – ACTAV 000041651), Batch 70298 (ACTAV 000041652 – ACTAV 000042030), Batch 70299 (ACTAV 000042031 – ACTAV 000042335), Batch 70300 (ACTAV 000042336 – ACTAV 000042632), Batch 70370 (ACTAV 000042633 – ACTAV 000043156), Batch 70371 (ACTAV 000043157 – ACTAV 000043403), Batch 70372 (ACTAV 000043404 – ACTAV 000043803), Batch 70386 (ACTAV 000043804 – ACTAV 000044081), Batch 70454 (ACTAV 000044082 – ACTAV 000044412), Batch 70455 (ACTAV 000044413 – ACTAV 000044678), Batch 70456 (ACTAV 000044679 – ACTAV 000045023), Batch 70457 (ACTAV 000045024 – ACTAV 000045302), Batch 70458 (ACTAV 000045303 – ACTAV 000045550), Batch 70551 (ACTAV 000045551 – ACTAV 000045939), Batch 70557 (ACTAV 000045940 – ACTAV 000046291), Batch 70558 (ACTAV 000046292 – ACTAV 000046601), Batch 70559 (ACTAV 000046602 – ACTAV 000046920), Batch 70560 (ACTAV 000046921 – ACTAV 000047255), Batch 70600 (ACTAV 000047256 – ACTAV 000047653), Batch 70601 (ACTAV 000047654 – ACTAV 000048017), Batch 70664 (ACTAV 000048018 – ACTAV 000048441), Batch 70665 (ACTAV 000048441 – ACTAV 000048820), Batch 70666 (ACTAV 000048821 – ACTAV 000049097), Batch 70670 (ACTAV 000049098 – ACTAV 000049553), Batch 70671 (ACTAV 000049554 – ACTAV 00004987), Batch 70672 (ACTAV 000049874 – ACTAV 000050183), Batch 70673 (ACTAV 000050184 – ACTAV 000050544), Batch 70736 (ACTAV 000050545 – ACTAV 000051062), Batch 70737 (ACTAV 000051063 – ACTAV 000051414), Batch 70738 (ACTAV 000051415 – ACTAV 000051754), Batch 70753 (ACTAV 000051755 – ACTAV 000052161), Batch 70766 (ACTAV 000052162 – ACTAV 000052611), Batch 70767 (ACTAV 000052611 – ACTAV 000053036), Batch 70768 (ACTAV 000053037 – ACTAV 000053547), Batch 70769 (ACTAV 000053548 – ACTAV 000053976), Batch 70770 (ACTAV 000053977 – ACTAV

000054490), Batch 70811 (ACTAV 000054491 – ACTAV 000054839), Batch 70812 (ACTAV 000054840 – ACTAV 000055172), Batch 70813 (ACTAV 000055173 – ACTAV 000055535), Batch 70832 (ACTAV 000055536 – ACTAV 000055793), Batch 70833 (ACTAV 000055794 – ACTAV 000056198), Batch 70834 (ACTAV 000056199 – ACTAV 000056489), Batch 70835 (ACTAV 000056490 – ACTAV 000056780), Batch 70836 (ACTAV 000056781 – ACTAV 000057138), Batch 70925 (ACTAV 000057139 – ACTAV 000057468), Batch 70826 (ACTAV 000057469 – ACTAV 000057807), Batch 70949 (ACTAV 000057808 – ACTAV 000058172), Batch 70950 (ACTAV 000058173 – ACTAV 000058544), Batch 70951 (ACTAV 000058545 – ACTAV 000058899), Batch 70952 (ACTAV 000058900 – 000059181), Batch 70953 (ACTAV 000059182 – ACTAV 000059460), Batch 71004 (ACTAV 000059461 – ACTAV 000060005), Batch 71005 (ACTAV 000060006 – ACTAV 000060576), Batch 71032 (ACTAV 000060577 – ACTAV 000061024), Batch 71034 (ACTAV 000061025 – ACTAV 000061473), Batch 71035 (ACTAV 000061474 – ACTAV 000061945), Batch 80111 (ACTAV 000061946 – ACTAV 000062448), Batch 80191 (ACTAV 000062449 – ACTAV 000062685), Batch 80192 (ACTAV 000062686 – ACTAV 000062959). See also the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 0000000095 – ACTAV 000002111.

**INTERROGATORY NO. 36:**

Please list all persons including employees, managers, directors or consultants, that you have demoted, transferred, suspended, financially penalized, discharged (whether voluntary or involuntary), disciplined or laid-off, for any reason in whole or in part, in the past three years,

- a) That has ever participated in the manufacturing of Digitek;
- b) That has ever participated in the Regulatory, Compliance or Quality Departments functions related to Digitek.

**RESPONSE TO INTERROGATORY NO. 36:**

Defendants object to this Interrogatory on the grounds that it is overbroad and is not

reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms “demoted, transferred, suspended, financially penalized, discharged (whether voluntary or involuntary), disciplined or laid-off.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants. Defendants further object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege.

**INTERROGATORY NO. 37:**

For each person listed in the answer to the above interrogatory, please list the reason for the action taken by Actavis.

**RESPONSE TO INTERROGATORY NO. 37:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term and phrase “reason” and “action taken by Actavis.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants. Defendants further object to this Interrogatory because it assumes foundational facts that are not in evidence. Defendants further object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege.

**INTERROGATORY NO. 38:**

How were HPLC results for Digitek® calculated before the implementation of Empower?

**RESPONSE TO INTERROGATORY NO. 38:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of



admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms “calculated” and “implementation.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Prior to implementation of Empower, HPLC results during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008, were calculated using Turbochrom/Totalchrom and Quattropro. In addition, a manual calculation was also performed.

**INTERROGATORY NO. 39:**

How was particle size or determined prior to implementation of “Malvern?”

**RESPONSE TO INTERROGATORY NO. 39:**

Defendants object to this Interrogatory to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms “particle size” and “implementation.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Prior to implementation of Malvern, during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008, particle size was determined using Cilas Particle Size Analyzer.

**INTERROGATORY NO. 40:**

Please list the total number of Digitek® pills that were recalled.

**RESPONSE TO INTERROGATORY NO. 40:**

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: There were 171 batches of Digitek® subject to the April 25, 2008 recall; 153 of the batches were actually released to the retail or consumer level and then recalled. See Defendants' response to Interrogatory No. 9. A theoretical batch of 0.125 mg Digitek® contains 4.8 million tablets. A theoretical batch of 0.250 mg Digitek® contains 4.2 million tablets. 83 batches of 0.125 mg Digitek®, theoretically 398,400,000 tablets, were recalled from the retail and consumer level; 70 batches of 0.25 mg Digitek®, theoretically 294,000,000 tablets, were recalled from the retail and consumer level. For precise number of tablets contained in each recalled batch, see records relating to each batch, including previously produced records relating to Batch 70924 (ACTAV 000002112 – ACTAV 000003336), Batch 60236 (ACTAV 000003337 – ACTAV 000003991), Batch 60371 (ACTAV 000003992 – ACTAV 000004240), Batch 60372 (ACTAV 000004241 – ACTAV 000004969), Batch 60373 (ACTAV 000004970 – ACTAV 000005216), Batch 60319 (ACTAV 000006733 – ACTAV 000007669), Batch 60320 (ACTAV 000007670 – ACTAV 000007846), Batch 60321 (ACTAV 000007847 – ACTAV 000008141), Batch 60322 (ACTAV 000008142 – ACTAV 000008307), Batch 60323 (ACTAV 000008308 – ACTAV 000008581), Batch 60399 (ACTAV 000008582 – ACTAV 000008912), Batch 60400 (ACTAV 000008913 –

ACTAV 000009153), Batch 60401 (ACTAV 000009154 – ACTAV 000009571), Batch 60402 (ACTAV 000009572 – ACTAV 000009834), Batch 60416 (ACTAV 000009835 – ACTAV 000010090), Batch 60497 (ACTAV 000010091 – ACTAV 000010249), Batch 60498 (ACTAV 000010250 – ACTAV 000010480), Batch 60499 (ACTAV 000010481 – ACTAV 000010657), Batch 60511 (ACTAV 000010658 – ACTAV 000010863), Batch 60512 (ACTAV 000010864 – ACTAV 000011041), Batch 60513 (ACTAV 0000011042 – ACTAV 000011197), Batch 60514 (ACTAV 000011198 – ACTAV 000011422), Batch 60515 (ACTAV 000011423 – ACTAV 000011585), Batch 60605 (ACTAV 000011586 – ACTAV 000011939), Batch 60606 (ACTAV 000011940 – ACTAV 000012270), Batch 60607 (ACTAV 000012271 – ACTAV 000012658), Batch 60608 (ACTAV 0000012659 – ACTAV 000012920), Batch 60643 (ACTAV 000012921 – ACTAV 000013511), Batch 60644 (ACTAV 000013512 – ACTAV 000013856), Batch 60645 (ACTAV 000013857 – ACTAV 000014119), Batch 60677 (ACTAV 000014120 – ACTAV 000014304), Batch 60678 (ACTAV 000014305 – ACTAV 000014584), Batch 60679 (ACTAV 000014585 – ACTAV 000014833), Batch 60680 (ACTAV 000014834 – ACTAV 000015021), and Batch 60681 (ACTAV 000015022 – ACTAV 000015230), Batch 60756 (ACTAV 000018757 – ACTAV 000019129), Batch 60757 (ACTA000019130 – ACTAV 000019422), Batch 60758 (ACTA000019423 – ACTAV 000019684), Batch 60759 (ACTAV 000019685 – ACTAV 000020107), Batch 60776 (ACTAV 000020108 – ACTAV 000020405), Batch 60777 (ACTAV 000020406 – ACTAV 000020667), Batch 60863, ACTAV 000020668 – ACTAV 000020907), Batch 60864 (ACTAV 000020908 – ACTAV 000021106), Batch 60865 (ACTAV 000021107 – ACTAV 000021291), Batch 60929 (ACTAV 000021292 – ACTAV 000021623), Batch 60930 (ACTAV 000021624 – ACTAV 000021922), Batch 60931 (ACTAV 000021923 – ACTAV 000022282), Batch 60932 (ACTAV 000022283 – ACTAV 000022844), Batch 60991 (ACTAV 000022845 – ACTAV 000023116); (ACTAV 000024284 – ACTAV 000024285), Batch 60992 (ACTAV 000023117 – ACTAV 000023998), Batch 60993 (ACTAV 000023999 –

ACTAV 000024352), Batch 60994 (ACTAV 000024353 – ACTAV 000024634), Batch 61053 (ACTAV 000024635 – ACTAV 000024796), Batch 61054 (ACTAV 000024797 – ACTAV 000025095), Batch 61055 (ACTAV 000025096 – ACTAV 000025328), Batch 61056 (ACTAV 000025329 – ACTAV 000025494), Batch 61057 (ACTAV 000025495 – ACTAV 000025745), Batch 61092 (ACTAV 000025746 – ACTAV 000025985), Batch 61097 (ACTAV 000025986 – ACTAV 000026163), Batch 61098 (ACTAV 000026164 – ACTAV 000026402), Batch 61099 (ACTAV 000026403 – ACTAV 000026605), Batch 61100 (ACTAV 000026606 – ACTAV 000026993), Batch 61101 (ACTAV 000026994 – ACTAV 000027346), Batch 61102 (ACTAV 000027347 – ACTAV 000027639), Batch 61103 (ACTAV 000027640 – ACTAV 000027916), Batch 61104 (ACTAV 000027917 – ACTAV 000028089), Batch 70023 (ACTAV 000029372 – ACTAV 000030541), Batch 70024 (ACTAV 000030542 – ACTAV 000031026), Batch 70025 (ACTAV 000031027 – ACTAV 000031415), Batch 70026 (ACTAV 000031416 – ACTAV 000031779), Batch 70027 (ACTAV 000031780 – ACTAV 000032194), Batch 70078 (ACTAV 000032195 – ACTAV 000033348), Batch 70079 (ACTAV 000033349 – ACTAV 000033715), Batch 70080 (ACTAV 000033716 – ACTAV 000034116), Batch 70081 (ACTAV 000034117 – ACTAV 000034630), Batch 70082 (ACTAV 000034631 – ACTAV 000034995), Batch 70120 (ACTAV 000034996 – ACTAV 000035324), Batch 70121 (ACTAV 000035325 – ACTAV 000035608), Batch 70122 (ACTAV 000035609 – ACTAV 000035907), Batch 70134 (ACTAV 000035908 – ACTAV 000036297), Batch 70135 (ACTAV 000033298 – ACTAV 000036647), Batch 70136 (ACTAV 000033348 – ACTAV 000036996), Batch 70147 (ACTAV 000036997 – ACTAV 000037406), Batch 70149 (ACTAV 000037407 – ACTAV 000037696), Batch 70160 (ACTAV 000037697 – ACTAV 000038158), Batch 70161 (ACTAV 000038159 – ACTAV 000038643), Batch 70174 (ACTAV 000038644 – ACTAV 000038993), Batch 70175 (ACTAV 000038994 – ACTAV 000039349), Batch 70176 (ACTAV 000039350 – ACTAV 000039643), Batch 70207 (ACTAV 000039644 – ACTAV 000040211), Batch 70208 (ACTAV 000040212 –

ACTAV 000040628), Batch 70209 (ACTAV 000040629 – ACTAV 000040982), Batch 70296 (ACTAV 000040983 – ACTAV 000041345), Batch 70297 (ACTAV 000041346 – ACTAV 000041651), Batch 70298 (ACTAV 000041652 – ACTAV 000042030), Batch 70299 (ACTAV 000042031 – ACTAV 000042335), Batch 70300 (ACTAV 000042336 – ACTAV 000042632), Batch 70370 (ACTAV 000042633 – ACTAV 000043156), Batch 70371 (ACTAV 000043157 – ACTAV 000043403), Batch 70372 (ACTAV 000043404 – ACTAV 000043803), Batch 70386 (ACTAV 000043804 – ACTAV 000044081), Batch 70454 (ACTAV 000044082 – ACTAV 000044412), Batch 70455 (ACTAV 000044413 – ACTAV 000044678), Batch 70456 (ACTAV 000044679 – ACTAV 000045023), Batch 70457 (ACTAV 000045024 – ACTAV 000045302), Batch 70458 (ACTAV 000045303 – ACTAV 000045550), Batch 70551 (ACTAV 000045551 – ACTAV 000045939), Batch 70557 (ACTAV 000045940 – ACTAV 000046291), Batch 70558 (ACTAV 000046292 – ACTAV 000046601), Batch 70559 (ACTAV 000046602 – ACTAV 000046920), Batch 70560 (ACTAV 000046921 – ACTAV 000047255), Batch 70600 (ACTAV 000047256 – ACTAV 000047653), Batch 70601 (ACTAV 000047654 – ACTAV 000048017), Batch 70664 (ACTAV 000048018 – ACTAV 000048441), Batch 70665 (ACTAV 000048441 – ACTAV 000048820), Batch 70666 (ACTAV 000048821 – ACTAV 000049097), Batch 70670 (ACTAV 000049098 – ACTAV 000049553), Batch 70671 (ACTAV 000049554 – ACTAV 00004987), Batch 70672 (ACTAV 000049874 – ACTAV 000050183), Batch 70673 (ACTAV 000050184 – ACTAV 000050544), Batch 70736 (ACTAV 000050545 – ACTAV 000051062), Batch 70737 (ACTAV 000051063 – ACTAV 000051414), Batch 70738 (ACTAV 000051415 – ACTAV 000051754), Batch 70753 (ACTAV 000051755 – ACTAV 000052161), Batch 70766 (ACTAV 000052162 – ACTAV 000052611), Batch 70767 (ACTAV 000052611 – ACTAV 000053036), Batch 70768 (ACTAV 000053037 – ACTAV 000053547), Batch 70769 (ACTAV 000053548 – ACTAV 000053976), Batch 70770 (ACTAV 000053977 – ACTAV 000054490), Batch 70811 (ACTAV 000054491 – ACTAV 000054839), Batch 70812 (ACTAV 000054840 –

ACTAV 000055172), Batch 70813 (ACTAV 000055173 – ACTAV 000055535), Batch 70832 (ACTAV 000055536 – ACTAV 000055793), Batch 70833 (ACTAV 000055794 – ACTAV 000056198), Batch 70834 (ACTAV 000056199 – ACTAV 000056489), Batch 70835 (ACTAV 000056490 – ACTAV 000056780), Batch 70836 (ACTAV 000056781 – ACTAV 000057138), Batch 70925 (ACTAV 000057139 – ACTAV 000057468), Batch 70826 (ACTAV 000057469 – ACTAV 000057807), Batch 70949 (ACTAV 000057808 – ACTAV 000058172), Batch 70950 (ACTAV 000058173 – ACTAV 000058544), Batch 70951 (ACTAV 000058545 – ACTAV 000058899), Batch 70952 (ACTAV 000058900 – 000059181), Batch 70953 (ACTAV 000059182 – ACTAV 000059460), Batch 71004 (ACTAV 000059461 – ACTAV 000060005), Batch 71005 (ACTAV 000060006 – ACTAV 000060576), Batch 71032 (ACTAV 000060577 – ACTAV 000061024), Batch 71034 (ACTAV 000061025 – ACTAV 000061473), Batch 71035 (ACTAV 000061474 – ACTAV 000061945), Batch 80111 (ACTAV 000061946 – ACTAV 000062448), Batch 80191 (ACTAV 000062449 – ACTAV 000062685), Batch 80192 (ACTAV 000062686 – ACTAV 000062959). See also the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 0000000095 – ACTAV 000002111.

**INTERROGATORY NO. 41:**

For each recalled batch, please list the distributor.

**RESPONSE TO INTERROGATORY NO. 41:**

Defendants object to this Interrogatory because it is improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Each batch of recalled Digitek® was distributed by Mylan Pharmaceuticals, Inc., Mylan Bertek

Pharmaceuticals, or UDL Laboratories, Inc.

**INTERROGATORY NO. 42:**

Please list the total number of prescriptions covered by the recall.

**RESPONSE TO INTERROGATORY NO. 42:**

Defendants object to this Interrogatory because it is improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Defendants do not possess any information that is responsive to this Interrogatory.

**INTERROGATORY NO. 43:**

Please describe how you track the distribution of Digitek® from the time the batch leaves Actavis until it reaches a consumer.

**RESPONSE TO INTERROGATORY NO. 43:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term and phrase “track” and “leaves Actavis.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.



Subject to the foregoing objections, Defendants respond as follows: Actavis distributes all Digitek® to Mylan Pharmaceuticals, Inc. and tracks distribution to Mylan Pharmaceuticals through sales and shipping documents reflecting and relating to Mylan's purchase of Digitek®. Actavis does not track distribution of Digitek® beyond Mylan to either the retail or consumer level.

**INTERROGATORY NO. 44:**

Please describe how you tracked pills once they were returned due to the recall including return to your custody, Mylan's custody, a pharmacy, a doctor or stericycle.

**RESPONSE TO INTERROGATORY NO. 44:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term "tracked." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants. Defendants further object to this Interrogatory because it assumes foundational facts that are not in evidence. Defendants further object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: No Digitek® tablets have been returned to Actavis due to the recall. Pursuant to the Digitek® recall notice, Digitek® returned due to the recall is returned to Stericycle, the third-party vendor hired by Mylan to coordinate the recall and receive all returned product. Actavis does not track any Digitek®



returned due to the recall.

**INTERROGATORY NO. 45:**

Referring you to page 11 of the ANDA Annual Report dated 2/21/05 covering the period of 1/1/2004 – 12/31/2004, produced as Bates ACTA000005697, where it states “thick tablet”... “tablet was left in vibrator during the set up of the machine and passed undetected,” please provide a detailed description of each and every fact relating to this referred to Adverse Event / AER, including but not limited to:

- a) the date that you received or gained knowledge of this Adverse Event / AER;
- b) how you gained knowledge of this Adverse Event / AER;
- c) who received the information about this Adverse Event / AER;
- d) the identity of the person or persons who reported any information about this Adverse Event / AER;
- e) the identity of the person or persons with the most knowledge about this Adverse Event / AER;
- f) each and every action you took in response to receiving or gaining knowledge of this Adverse Event / AER, including investigating it and reporting it to the FDA (including the date you reported it, if you did so);
- g) any actions or measure you took to address or remedy this Adverse Event / AER;
- h) identify all persons who on your behalf, whether an employee, consultant, or other person was involved with addressing, remedying or taking any action regarding this Adverse Event / AER;
- i) identify each and every document related, generated from, exchanged between you and the FDA, relating to this Adverse Event / AER;
- j) identify any of your employees, managers, officers, directors, or consultants disciplined, reprimanded, given a written or verbal warning, terminated / fired /

discharged, suspended voluntarily or involuntarily laid off or retired, in any way as a result of the Adverse Event / AER.

**RESPONSE TO INTERROGATORY NO. 45:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. The inclusion of the phrase “including but not limited to...” also makes this Interrogatory overbroad. This Interrogatory is also vague and confusing as written with respect to the undefined terms and phrases “received or gained knowledge” and “disciplined, reprimanded, given a written or verbal warning, terminated / fired / discharged, suspended voluntarily or involuntarily laid off or retired, in any way as a result.” Defendants also object on the grounds that the requested information may infringe upon the privacy interests of patients or physicians or violate federal or state privacy laws or regulations, including 21 C.F.R. § 20.63(f). This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See Defendants’ responses to Interrogatory, No. 6, and to Requests for Production of Documents, Nos. 24, 25, 26, and 27.

**INTERROGATORY NO. 46:**

With regard to the tightened AGQL inspection and the AQL Sample Plan or Investigation 07-093 for Lot 70924A1, please state the following:

- a) whether the FDA was advised, consulted or notified about the AQL inspection and/or

the AQL Sample Plan before both were implemented, and if so, when and who was in contact with the FDA;

- b) whether the FDA approved the AQL inspection and/or the AQL Sample Plan before both were implemented;
- c) identify the person or persons at the FDA who had knowledge of the AQL inspection and/or the AQL Sample Plan prior to implementation by you;
- d) identify each person or person involved how the AQL inspection and AQL Sample Plan were to be conducted / implemented;
- e) identify each person or persons involved with defining the parameters of the AQL Sample Plan was;
- f) identify any standard, regulation, protocol, procedure, or methodology that you used to develop and define the AQL Sample plan;
- g) state each and every reason why as part of the AQL Sample Plan you selected 1250 tablets as the minimum number of tables to inspect;
- h) state each and every reason why as part of the AWL Sample Plan you decided to “Accept on 1 / Reject on 2 (total for batch) as stated on ACTAV 000002615;
- i) identify any standard, regulation, protocol, procedure, or methodology, that you relied on when, as part of the AQL Sample Plan, you decided to “Accept on 1 / Reject on 2 (total for batch) as stated on ACTAV 000002615;
- j) how many of the 4,747,428 (4,800,000 Theoretical) tablets you inspected;
- k) identify any and all equipment utilized during the AQL inspection and AQL Sample Plan to inspect the tablets;
- l) state the inspection criterion used by you during the tightened AQL inspection and the AQL Sample Plan; and
- m) identify each and every person that inspected tablets during the tightened AQL

inspection and the AQL Sample Plan.

**RESPONSE TO INTERROGATORY NO. 46:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms and phrases “tightened,” “implemented,” “implementation,” “defining the parameters,” “standard, regulation, protocol, procedure, or methodology that you used to develop and define,” and “inspection criterion used by you.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows:

- a) No.
- b) No.
- c) See response to a) above.
- d) Defendants cannot respond to this subsection because it is unintelligible as written.  
See documents previously produced as ACTAV 000002576 -- ACTAV 000002643.
- e) Dan Bitler and Scott Talbot. See documents previously produced as ACTAV 000002576 -- ACTAV 000002643.
- f) MIL-STD-105E.
- g) The minimum number of tablets to sample is prescribed by MIL-STD-105E for a Tightened AQL Level 1 inspection.

- h) The acceptance criteria are prescribed by MIL-STD-105E for a Tightened AQL Level 1 inspection.
- i) MIL-STD-105E.
- j) Every one of the 4,747,428 tablets in Batch 70924A was visually inspected.
- k) At the time of the Tightened AQL Inspection, the tablets from Batch 70924A were being held in 33 full buckets and a partially full 34th bucket. The appropriate numbers of random sample tablets were removed from different locations of each bucket using a scoop and then were inspected.
- l) See documents previously produced as ACTAV 000002576 – ACTAV 000002643.
- m) See documents previously produced as ACTAV 000002576 – ACTAV 000002643.

Dated: July 24, 2009

TUCKER ELLIS & WEST LLP

By: /s/ Richard A. Dean

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**CERTIFICATE OF SERVICE**

A copy of Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC's Responses to Plaintiffs' Second Set of Interrogatories was sent via electronic mail this 24<sup>th</sup> day of July, 2009 to:

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